DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 6, 2015

Or-Nim Medical Ltd.
Micha Oestereich
Quality Assurance/Regulatory Affairs Director
15 Atir Yeda St.
Kfar Saba, 446312
Israel

Re: K150268
Trade/Device Name: CerOx Model 3215FOP
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular blood flowmeter
Regulatory Class: Class II
Product Code: DPW
Dated: October 13, 2015
Received: October 15, 2015

Dear Mr. Oestereich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K150268

Device Name: CerOx Model 3215FOP

Indications for Use:

The non-invasive CerOx 3215FOP monitor is intended for use as an adjunct monitor of microcirculation blood flow in tissue.
The CerOx3215FOP monitor is intended for monitoring of newborn - adult.

The prospective clinical value of data from the CerOx 3215FOP monitor has not been demonstrated in disease states. The CerOx 3215FOP monitor should not be used as the sole basis for diagnosis or therapy.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(K) SUMMARY

Submission Date: January 14, 2015

Submitter Information:

Company Name:
Or-Nim Medical Ltd.

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Device Information:

Trade Name:	CerOx Model 3215FOP
Common Name:	Flowmeter, blood, cardiovascular
Classification Name:	Cardiovascular blood flowmeter (21 CFR 870.2100)
Product Code:	DPW
Regulatory Class:	II

Predicate Devices:
- CerOx 3210FO, Or-Nim Medical Ltd. (K131854)
- Fore-Sight Absolute Tissue Oximeter, CAS MED (K112820)

Device Description: The CerOx Model 3215FOP uses the well-established principles of near infrared spectroscopy (NIRS) and flowmetry to monitor blood flow in tissue.

CerOx Model 3215FOP is identical to the CerOx Model 3210FO technically and operationally.

Intended Use: The CerOx Model 3215FOP is intended to monitor blood flow in tissue

Indications for Use: The non-invasive CerOx 3215FOP monitor is intended for use as an adjunct monitor of microcirculation blood flow in tissue.
The CerOx3215FOP monitor is intended for monitoring of newborn - adult.
The prospective clinical value of data from the CerOx 3215FOP monitor has not been demonstrated in disease states. The CerOx 3215FOP monitor should not be used as the sole basis for diagnosis or therapy.

Comparison to Predicate Device: The CerOx 3215FOP is identical to the sited predicate devices related to the Indication for Use, technically and operationally with respect to blood flow monitoring.

Performance Testing: There is no Bench testing included in this 510(k).
There is no animal testing included in this 510(k).

Clinical Studies: There is no clinical testing included in this 510(k).

Conclusions: The modified model, the CerOx 3215FOP remains as safe and effective as, and remains substantially equivalent to the cleared predicate devices the CerOx 3210FO and the Fore-Sight Absolute Tissue Oximeter for the monitoring of microcirculation blood flow in tissue as indicated in the Indication for Use.